

From: Thompson, Edward
Sent: Monday, May 04, 2015 8:23 AM
To: 'Michelle Taylor'
Cc: Maruna, Thomas (Thomas.Maruna@fda.hhs.gov)
Subject: URGENT: Information Request for BL 125488/0

Importance: High

Contacts: Michelle Taylor

Dear Ms. Taylor:

We are reviewing your March 16, 2013 biologics license application (BLA) for Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection. We are providing the following comments and request for additional information to continue our review:

1. The PK study dose is different from the licensed dose.
2. Please confirm the dose of Anavip that was used in the Phase I Biosafety Study YA-06/07. The text states on page 3/31 of the report for A-06/07 that 1.86 mg of Anavip (1 vial) was given to each subject. We note that the current amount of Anavip/vial is 120 mg.



~~125488/06 PK...~~

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by May 4, 2013 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is May 6, 2015.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me at (240) 402-8443.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/PPMS